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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOHNSEN, JASON H	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,647	SAS ET AL.	
	Examiner	Art Unit	
	Jason H. Johnsen	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *N/A* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on February 23, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Comments regarding office action have been provided drawn to:
- (i) Newly cited claim objection is established below.
- (ii) Newly cited 112, 1st paragraph rejections of claims 1-4, 8-10 and newly cited 11, and 12 is established below.
- (iii) Newly cited 112, 2nd paragraph rejection of claims 1, 3, 4 and 12 is established below.

2. Claims 1-4, 8-10, and newly added claims 11 and 12 are pending in the case.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-4, and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain furonase compounds to treat herpesviridae , does not reasonably provide enablement for thiophene (X=S) or pyrrolidine (X=N) compounds to treat poxiridae or poxiviridae, Vaccinia virus or Cytomegalovirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

These claims are directed to the treatment of a family of viral infections—herpesviridae or poxviridae. Furthermore, claim 8 and claim 9 are drawn to subspecies of the genus family,

both of which have further subspecies (Cytomegalovirus and Vaccinia virus-see websites http://www.ncbi.nlm.nih.gov/ICTVdb/Ictv/fs_herpe.htm and <http://www.ncbi.nlm.nih.gov/ICTVdb/Ictv/fs_poxvi.htm). The claimed utility is an extraordinary one in that it is not limited to the viruses disclosed in the specification but rather asserts that administration of these compounds is effective against the full complex of these family or genus of viral infections.

Despite the colossal amount of research, since viruses were first identified as infective agents no one has found an agent that is effective against all viruses. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

The situation with viruses may be contrasted with that for bacterial infections. Certain agents, especially tetracycline and β-lactams are routinely found effective against a broad range of bacteria species. Thus, antibiotic activity against a gram-positive species means that activity might be expected against against all Gram-positive bacteria. The clinician uses this knowledge to prescribe a penicillin without determining which bacterium is responsible for the infection.

A far different situation prevails for viruses. Commonly an antiviral agent will be effective against a single species but not effective against other viruses in the same genus. What few antiviral agents exist are effective against only a limited range of viruses. Amantadine has

some effect on Influenza A but is ineffective against Influenza B or C. Foscavir is effective against HSV-1 and HSV-2 but ineffective against VZV. All three viruses are herpes viruses. Acyclovir, the most widely used agent for herpes is not effective against virus corneal epithelial herpes. AZT, part of the widely used treatment for HIV is not effective against DNA containing viruses. 5-FU, applied topically is effective against the human papilloma virus but has no effect against RNA viruses systemically or topically. Rabies has been known for hundreds of years. It is treated with a specific vaccine, which of course is ineffective against any other species of virus. No small molecule treatment of rabies is known. This lack of general efficacy in the antiviral arts means that a clinician is required to identify the species of viruses causing the disease before beginning treatment. This is in sharp contrast to the situation with bacteria.

The same situation prevails with the prevention of viral diseases by vaccines. No vaccine, effective to prevent all viral infections has ever been found. Current immunological knowledge of the antigenic variability of viral protein coats between different species explains this well. The HIV virus is notorious for its ability of one species of virus to rapidly evolve this outer protein, thus making an anti-HIV vaccine so for unattainable.

Most viruses have no effective treatment. There are two genuses of human retroviruses, each with two know species. These are HIV and HTLV. Other retroviruses infect mice, birds, cats etc. By dint of unprecedented chemical effort, a group of agents effective against HIV in man has been developed. None of these agents has been shown effective against HTLV or retroviruses in other species. Rotaviruses, which commonly lead to osmotic diarrhea in young children, and astroviruses and corona viruses, which commonly cause diarrhea in adults, have no effective treatment. Caliciviruses (Norwalk, Kawaii, Snow Mountain, etc.) cause gastroenteritis

and are so poorly understood that even classification is uncertain. Vast numbers of people get measles, some victims develop the complications of croup, conjunctivitis, and bacterial pneumonia, yet there is no treatment. The enteroviruses are a dangerous category that includes three polioviruses, 30 Coxsackie viruses, and a like number of echoviruses. These cause all manner of paralytic disease, often with permanent damage or death and are widespread throughout the world. In spite of the motivation that the death and disease caused by enteroviruses provides, there is no known anti-viral treatment.

This reason for the efficacy of antiviral agents against only a limited range of viruses is clear. The approaches to viral treatment that have been fruitful take advantage of precisely defined molecular features of the virus and have recently resulted in effective therapy for herpes and AIDS. The best targets for inhibition by antiviral are theoretically molecules serving a function unique to the virus. Viruses code for few enzymes that are vulnerable to chemical attack. Each virus tends to have its own set of enzyme systems. Viruses are classified on physical but not molecular features. It is optimistic in the extreme to believe that given the history of anti-viral research that an agent will be effective on such a diverse class of viruses that share physical but not molecular features. The rejected claims call for the treatment of these broad family and subfamily or subgenus of viruses generally. Therefore, applicant should limit claims to what has support in the specification—furonase compounds to treat herpesviridae viruses.

2. Claims 1-4, and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description in that application does not have a possession for compounds of formula in claim 1, wherein X is Nitrogen or Sulfur.

The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventors had possession of the claimed invention as of the filing date relied upon.

In the instant case, the specification only teaches that X is oxygen, forming furanose compounds (see examples pages 8-19 in spec). However, the claims encompass the scope of X being Nitrogen or Sulfur.

To provide adequate written description and evidence of possession of a claimed genus formula of compounds, the specification must provide sufficient distinguished identified characteristics of the genus formula. The factors to be considered include the physical and/or chemical properties, functional characteristics, structural/functional correlation, and methods of making the claimed product or any combination thereof.

In the present case, there is no limitation regarding any of these aforementioned factors to the claimed genus formula of compounds. Vas-Cath V. Makurkar, 19USPQ 2d. 111, clearly states "applicant must convey with reasonable clarity to those skilled in the art, as of the filing date sought, he or she was in possession of the invention. The invention is, for purpose of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification should "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented

what is claimed." (see Vas-Cath page 1116). Moreover, to be in the possession of any claimed invention, the applicants must show that a significance of conception and reduction to practice was reached before the application was filed.

As discussed above, the skilled artisan cannot envision the detail chemical structure of encompassed genus of formula in Claim 1 comprising the substituents of X to be anything other than Oxygen. An adequate written description requires more than a mere submission of a general formula with a myriad of Markush style variables. The compound itself is required.

Therefore, only compounds that form furanose compounds meet the written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3, 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 3 and 4 recites the limitation "wherein R1 and R2 form a ring.." and "wherein R3 and R4 form a ring...". There is insufficient antecedent basis for this limitation in the claim. In amended claim set, neither R1 and R2 or R3 and R4 can form a ring.

2. Claim 12 is rejected for the same reason as claim 1. Claim 12 is an exact duplicate of claim 1.

3. Claim 1 recites the limitation of "poxiridae." This is indefinite because it is not known whether the applicant means to treat poxiridae, which is a genus of animal viruses, or "poxiviridae," which is a family of human viruses.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**. The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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